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08/484928

BACKGROUND OF THE INVENTION

Related Applications

¹ This application is a continuation in part of copending United States application Serial No. 08/396,414 filed on February 27, 1995 which is a continuation-in-part of United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247, all of which are incorporated herein by reference.

² This application is also a continuation-in-part of United States application Serial No. 08/390,131 entitled Interbody Spinal Fusion Implants filed on February 17, 1995.

Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated

with a loss of lordosis.

Therefore, there exists a need for spinal fusion implants that permit for the restoration of anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration to achieve a desired anatomical lordosis of the spine. In the preferred embodiment, the spinal fusion implants of the present invention have an outer locus in which at least some of the points of the implant comprise a partially or fully frusto-conical shape substantially along those portions of the implant in contact with the adjacent vertebrae of the spine and have an insertion end and a trailing end. The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a frusto-cone, at least one side portion may be truncated to form a planar surface that is parallel to the central longitudinal axis of the implant to form straight walls. These implants may have a more tapered aspect at the insertion end of the implant to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone ingrowth and stability.

The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes, may pass either into or through the implant and may or may not intersect. The spinal fusion implants of the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant. Said chamber may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means. Still further, a variety of surface irregularities may be employed to increase implant

stability and implant surface area, and/or for the purpose of allowing the spinal fusion implant to be inserted easily but to resist motion in the opposition direction. The exterior of the spinal fusion implant of the present invention may have wholly or in part, a rough finish, knurling, forward facing ratchetings or other surface irregularities sufficient to achieve the purpose described.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape, those that taper from the leading edge to the trailing edge are easy to introduce and easy to fully insert into the spinal segment to be fused.
2. The shape of the implants of the present invention is consistent with the shape of the disc, which the implants at least in part replace, wherein the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.
3. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics or combination sufficient for the intended

purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material and/or may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be loaded with, composed of, treated or coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

It is still another object of the present invention to provide a spinal fusion implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

It is still further another object of the present

invention to provide a spinal fusion implant that is consistent in use with the preservation of a uniform thickness of the subchondral vertebral bone;

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to an easily produced complementary bore at the fusion site; and

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual heights of each implant.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of an embodiment of the spinal fusion implant of the present invention having a frusto-conical body and a surface configuration comprising ratchetings for engaging bone, with wells and channels for bone ingrowth.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 2 is a cross sectional view along line 2--2 of the implant of Figure 1 illustrating the channels and wells of the implant of the present invention.

Figure 3 is a cross sectional view along line 3--3 of the implant of Figure 1 illustrating the channels and wells of the implant of the present invention.

Figure 3A is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and a plurality of ratchetings forming a cylindrical external configuration.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention

having truncated sides forming a planar surface parallel to the longitudinal axis of the implant and ratchetings having a radius and height that are not constant.

Figure 5 is a top plan view of the spinal fusion implant shown in Figure 4.

Figure 6 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is made out of a fibrous mesh-like material that is partially frusto-conical with one side that is truncated shown next to an identical second implant illustrated in hidden line.

Figure 7 is sectional view along line 7--7 of the implants of Figure 6.

Figure 8 is an enlarged fragmentary view along line 8 of Figure 6 illustrating the surface configuration of the implant of Figure 6.

Figure 9 is an enlarged fragmentary view along line 8 of Figure 6 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 10 is a cross sectional view along lines 10--10 of Figure 9 illustrating the alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 11 is a side elevational view in partial cut-away of an alternative embodiment of the spinal fusion implant of the present invention having a body that is frusto-conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 12 is an enlarged fragmentary sectional view along lines 12--12 of Figure 11 illustrating the surface configuration of the implant of Figure 11.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, an embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 220. The implant 220 has a frusto-conical body 222

and an outer locus that is generally frusto-conical substantially along the portion of the implant 220 that is in contact with the adjacent vertebrae of the spine. The implant 220 has a surface configuration of forward facing ratchetings 240 suitable for engaging the bone of the adjacent vertebrae. Each of the plurality of ratchetings 240 has a bone engaging edge 242 and ramped portion 244. The ratchetings 240 have a radius R_1 measured from the central longitudinal axis L_1 of the implant 220 that increases from the insertion end 224 to the trailing end 226. The height of the ratchetings 240 measured from the body 222 is constant throughout the length of implant 220.

The orientation of the ratchetings 240 makes the insertion of the implant 220 easier than its removal, as the ramped portions 244 act as an inclined plane on the way in, while the bone engaging edges 242 resist motion in the opposite directions. These forward facing ratchetings 240 tend to urge the implant 220 forward until the unremoved bone of the vertebrae blocks further motion resulting in a very stable spine and implant construct.

The implant 220 has a recessed slot 234 at its trailing end 226 for receiving and engaging insertion instrumentation for inserting the implant 220. The recessed slot 234 has a threaded opening 236 for threadably attaching the implant 220 to instrumentation used for inserting the implant 220.

In the preferred embodiment, the bone engaging edges 242 of the ratchetings 240 have a height at a highest point measured from the body 222 (root diameter) of the implant 220 in the range of 0.25 - 2.0 mm, with the preferred height being 0.4 mm for use in the cervical spine and 1.25 mm for use in the lumbar spine.

Referring to Figures 2 and 3, cross sectional views of implant 220 are shown. The implant 220 has channels 250 passing through the implant 220 and wells 260 formed in the surface of the implant 220. The wells 260 may or may not communicate with the channels 250. In the preferred embodiment of implant 220, the channels 250 have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The wells 260 have a diameter

in the range of 0.1 mm to 6 mm, with 1-3 mm being the preferred diameter range. It is appreciated that although the channels 250 and wells 260 are shown having a generally rounded configuration, it is within the scope of the present invention that the channels 250 and wells 260 may have any size, shape, configuration, and distribution suitable for the intended purpose.

Referring to Figure 1A, the implant 220 has an outer surface 238 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface 238 is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. It is appreciated that the outer surface 238, and/or the entire implant 220, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant 220 may be further coated with bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 220 is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

^{F3} While the implant 220 is shown as being solid, it is appreciated that the implant 220 can be hollow at least in part to provide an internal chamber for holding bone or any fusion promoting material. Such an implant could have openings to allow bone external to the implant to grow into the internal chamber. Such structure is disclosed in detail in co-pending application serial no. 08/390,131, ^{now U.S. Patent 5,593,409} and co-pending application serial no. 08/074,781, ^{now U.S. Patent 5,484,437}, both of which are incorporated herein by reference.

^{F4} Referring to Figure 3A, an alternative embodiment of the implant 220 is shown and generally referred to by the numeral 220'. The implant 220' is similar in configuration to implant 220 except that the body 222' of the implant is frusto-conical in configuration and the ratchetings 240' have a radius R, measured from the longitudinal central axis L, that is constant in size from

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the insertion end 224' to the trailing end 226'. The ratchetings 240' each have a height measured from the body 222' that is not constant throughout the length of the implant 220' and decreases from the insertion end 224' to the trailing end 226'. In this manner, the ratchetings 240' form an external configuration of the implant 220' that is substantially cylindrical in shape, while the body 220' is frusto-conical. The insertion end of implant 220' may have a tapered portion 223' of lesser diameter to facilitate insertion of the implant 220'.

^{FS} Referring to Figures 4 and 5, an alternative embodiment of the implant 220 is shown and generally referred to by the numeral 220''. The implant 220'' is similar in configuration to implant 220 and has ratchetings 240'' having a radius R_s measured from the longitudinal central axis L_s that increases in size from the insertion end 224'' to the trailing end 226''. The ratchetings 240' each have a height measured from the body 222'' that is not constant throughout the length of the implant 220''. In the preferred embodiment, the ratchet radius R_s and the ratchet height increase in size from the insertion end 224'' to the trailing end 226''.

^{FL6} As shown in Figure 5, the implant 220'' has truncated sides 270 and 272 forming two planar surfaces which are diametrically opposite and are parallel to the longitudinal axis L_s . In this manner, two implants 220'' may be placed side by side with one of the sides 270 or 272 of each implant touching, such that the area of contact with the bone of the adjacent vertebrae and the ratchetings 240'' is maximized. Alternatively, the implant 220'' may have one truncated side.

Referring to Figures 6-8, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 320a. The implant 320a is shown placed next to a second identical implant 320b shown in hidden line. The implant 320a has a body 322 that is made of a mesh-like material comprising strands, which may be made of metal, that are pressed together and molded into a partially frusto-

conical configuration substantially along the portion of the implant 320a in contact with the adjacent vertebrae of the spine. The implant 320a has an insertion end 324 and a trailing end 326 and may be made wholly or in part of a solid material and/or a porous material, and/or a mesh-like material. The implant 320a may have a surface comprising of a porous material, a mesh-like material, or have a surface that is roughened. It is appreciated that the implant 320a may be solid or may be partially hollow and include at least one internal chamber. As shown in Figure 8, the mesh-like material comprises strands that are formed and pressed together such that interstices 339, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 338 of implant 320a.

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F7 Referring to Figures 9 and 10, alternatively the implant 320a may be made of a cancellous material 350, similar in configuration to human cancellous bone, having interstices 352 such that the outer surface 338 has a configuration as shown in Figures 9 and 10. As the implant 320a may be made entirely or in part of the cancellous material 350, the interstices 352 may be present in the outer surface 338 and/or within the entire implant 320a to promote bone ingrowth and hold bone fusion promoting materials.

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FB Referring again to Figure 7, the implant 320a is partially frusto-conical, similar in shape to implant ²²⁰20 but having at least one truncated side 340 that forms a planar surface parallel to the central longitudinal axis of implant ^{320a}320. The truncated side 340 allows for the placement of two implants 320a and 320b closer together when placed side by side between two adjacent vertebrae as set forth in U.S. Patent Application Serial No. 08/390,131, incorporated herein by reference. Implant 320a may be partially threaded or may otherwise resemble any of the other embodiments herein described or that are functionally equivalent.

Referring to Figure 11, a side elevational view in partial cut-away of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral

420. The implant 420 has a body 422 that is frusto-conical in shape substantially along the portion of the implant 420 that is in contact with the adjacent vertebrae of the spine and has an insertion end 424 and a trailing end 426. The implant 420 has an outer surface 438 that is capable of receiving and holding bone, or other materials capable of participating in the fusion process and/or capable of promoting bone ingrowth. In the preferred embodiment, the surface 438 comprises a plurality of posts 440 that are spaced apart to provide a plurality of interstices 442 which are partial wells with incomplete walls capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. The implant 420 may be prepared for implantation by grouting or otherwise coating the surface 438 with the appropriate fusion promoting substances.

Referring to Figure 12, an enlarged view of the surface 438 of implant 420 is shown. In the preferred embodiment, the posts 440 have a head portion 444 of a larger diameter than the remainder of the posts 440, and each of the interstices 442 is the reverse configuration of the posts 444, having a bottom 446 that is wider than the entrance 448 to the interstices 442. Such a configuration of the posts 440 and interstices 442 aids in the retention of bone material in the surface 438 of the implant 420 and further assists in the locking of the implant 420 into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom ⁴⁴⁶~~446~~ of the interstices 442 is wider than the entrance 448, the bone ingrowth cannot exit from the entrance 448 and is locked within the interstice 442. The surface 438 of the implant 420 provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non-smooth surface.

In the preferred embodiment, the posts 440 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 442 have a width in the range of approximately 0.1 to 2 mm. The post sizes, shapes,

and distributions may be varied within the same implant.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.